IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Schuler et al. Application No: 10/601,127 Confirmation No: 5998 Filed: June 19, 2003 Title: SYSTEMS AND METHODS FOR AEROSOLIZING PHARMACEUTICAL FORMULATIONS	Group Art Unit: 3773 Examiner: Darwin P. EREZO Attorney Docket No: 53243-US-CNT[2] (NK.0047.10) September 10, 2009 San Francisco, California 94107

APPEAL BRIEF

VIA ELECTRONIC FILING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of March 10, 2009 and the Notice of Appeal filed on June 10, 2009, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

Certificate of Transmission

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By: Amy Wells Date: September 10, 2009

(1) *Real Party in Interest*

The real party in interest of the present application is Novartis AG (by way of assignment from Novartis Pharmaceuticals AG and from Nektar Therapeutics, which was formerly Inhale Therapeutic Systems, Inc.), having a place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

(2) *Related Appeals and Interferences*

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 53-60 are presently pending in the case. Claims 53-60 have been finally rejected. The rejection of each of claims 53-60 is hereby appealed.

Claims 1-52 have been cancelled.

(4) *Status of Amendments*

No amendments have been filed after Final Office Action. Accordingly, all amendments submitted during prosecution have been entered.

(5) *Summary of the Claimed Subject Matter*

As recited in claim 53, a method for aerosolizing a pharmaceutical formulation comprises providing a valve (see element 14 in Figure 4 and the discussion on page 18 lines 3-8) within an airway leading to the lungs. The valve prevents respiratory gases from flowing to the lungs when a user attempts to inhale, and then abruptly permits

respiratory gases to flow to the lungs by opening when a threshold actuating vacuum caused by the attempted inhalation is exceeded. The method further comprises providing a separate flow regulator (see element 18 in Figure 4 and the discussion on page 18 lines 8-19) within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases. The flow resistance through the flow regulator is low when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases thereafter (see page 29 lines 30-35). The flow of respiratory gases are used to extract a pharmaceutical formulation from a receptacle (see element 12 in Figure 4) and to place the pharmaceutical formulation within the flow of respiratory gases to form an aerosol.

(6) *Grounds of Rejection to be Reviewed on Appeal*

Appellant requests review of the Examiner's following grounds of rejection:

Claims 53-55, 57 and 59 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,727,546 to Clarke et al (hereinafter Clarke et al).

Claim 56 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Clarke et al.

Claims 58 and 60 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Clarke et al in view of U.S. Patent 6,116,237 to Schultz et al (hereinafter Schultz et al).

(7) *Argument*

Appellant believes each of claims 53-60 are improperly rejected and are therefore allowable for the following reasons.

The rejections under §102(b) are improper

The Examiner's rejection of claims 53-55, 57 and 59 under 35 USC §102(b) as being anticipated by Clarke et al is improper and should be reversed.

Clarke et al does not anticipate independent claim 53, for example. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation.

Claim 53 is a method for aerosolizing a pharmaceutical formulation, the method comprising, inter alia, providing a valve to prevent respiratory gases from flowing to the lungs when a user attempts to inhale, and then abruptly permitting respiratory gases to flow to the lungs by opening the valve when a threshold actuating vacuum caused by the attempted inhalation is exceeded, and providing a flow regulator within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases. Clarke et al does not provide both a threshold valve as claimed and a flow regulator as claimed. It is respectfully submitted that these positively recited features are absent in the disclosure of Clarke et al, thereby precluding a section 102 rejection because each and every element of the claim is not taught by the cited reference.

The Examiner directs the Appellant's attention to the embodiment of Clarke et al. shown in Figures 2(a)-2(c). However, this embodiment of Clarke et al discloses a single valve 27 and does not disclose a separate threshold valve and flow regulator. Referring to column 8 lines 20-43 of Clarke et al, Clarke et al considers valve 27 a flow regulator.

There is no mention of valve 27 also being a threshold valve. Nothing within the discussion of the operation of valve 27 indicates that the valve 27 has properties similar to those of a threshold valve. For example, column 8 lines 28-31 recite that "**on inhalation**, vane 27 rotates ... allowing the flow of air" (emphasis added). Since the flow is allowed "on inhalation" it is apparent that there is nothing that prevents respiratory gases from flowing to the lungs when a user attempts to inhale, as required by claim 53. Since all elements of claim 53 are not accounted for in Clarke et al, Clarke et al does not anticipate claim 53.

Even assuming, *in arguendo*, that valve 27 of Clarke et al could be considered by itself both a threshold valve and a separate flow regulator, the valve 27 would still lack all features positively recited in claim 53. For example, claim 53 recites "wherein the flow resistance through the flow regulator is low when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases thereafter." Valve 27 of Clarke et al does not operate in this manner. Before respiratory gases flow, the Clarke et al valve is in the position shown in Figure 2(a). As respiratory gases are permitted to flow, the valve (27) of Clarke et al rotates counterclockwise from the position shown in Figure 2(a). In going from the position shown in Clarke et al's Figure 2(a) to the position shown in Figure 2(b), the flow resistance decreases, i.e. the opening caused by the movement of element 27 increases. Thus, the flow resistance is not low when gases are permitted to flow and then increases, as required by claim 53. Instead, the flow resistance of Clarke et al is high when respiratory gases begin to flow and then decreases up until the position shown in Figure 2(b).

The Examiner's comments concerning the Figure 2(a)- 2(c) embodiment in the Final Office Action of March 10, 2009 do not serve to advance the Examiner's position. The Examiner points out that the flow resistance of Clarke et al increases in going from the position of Figure 2(b) to the position of Figure 2(c). However, the Examiner's point is immaterial to the issue at hand. The claim 53 recitation at issue relates to when the respiratory gases are first permitted to flow. The Examiner, on the other hand, improperly chooses a starting point that occurs after the respiratory gases have been

flowing. The Examiner ignores the decreasing flow resistance in Clarke et al when going from the position of Figure 2(a) to the position of Figure 2(b). Appellant respectfully suggests that the Examiner's interpretation of Clarke et al is unreasonable and not consistent with an interpretation one of ordinary skill in that art would make.

Appellant requests reversal of the rejection of claim 53 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 54, 55, 57 and 59 which depend from claim 53 and are not anticipated by Clarke et al for at least the same reasons as claim 53.

The rejections under §103(a) based on Clarke et al are improper

The Examiner's rejection of claims 58 and 60 under 35 USC 103(a) as being unpatentable over Clarke et al is improper and should be reversed.

Clarke et al does not render claims 58 and 60 unpatentable. Claims 58 and 60 depend from claim 53 which is not rendered unpatentable by Clarke et al for the reasons given above. Since claims 58 and 60 depend from an allowable claim, they too are allowable.

In addition, claim 58 is allowable over Clarke et al in that Clarke et al fails to disclose or teach the duckbill valve recited in the claim. Claim 60 is also not rendered unpatentable by Clarke et al in that claim 60 recites a parallel flow arrangement that is not disclosed or taught by Clarke et al. The Examiner makes baseless allegations that these features would have been obvious to one of ordinary skill in the art. The Examiner provides no evidence or convincing reasoning in support of this contention and therefore has failed to establish a prima facie case under 35 U.S.C. § 103(a).

For at least these reasons, claims 58 and 60 are not properly rejectable under 35 USC §103(a) as being unpatentable over Clarke et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary

For at least these reasons, claims 58 and 60 are not properly rejectable under 35 USC §103(a) as being unpatentable over Clarke et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the suggested modifications could be applied, with a reasonable likelihood of success, to Clarke et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined the teachings in a manner that would result in the invention of claims 58 and 60, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claims 58 and 60 are allowable over the references cited.

Appellant requests reversal of the rejection of claims 58 and 60 under 35 U.S.C. §103(a).

The rejections under §103(a) based on Clarke et al and Schultz et al are improper

The Examiner's rejection of claim 56 under 35 USC 103(a) as being unpatentable over Clarke et al in view of Schultz et al is improper and should be reversed.

Claim 56 depends from allowable claim 53. Schultz et al is not relied upon to make up for the deficiencies of Clarke et al, nor does it. Since Schultz et al does not make up for these deficiencies, the combination of Clarke et al and Schultz et al fails to render independent claim 53 unpatentable. Claim 56 depends from claim 53 and is therefore also allowable over the combination of references. Appellant requests reversal of the rejection.

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: September 10, 2009

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(8) Claims Appendix

53. A method for aerosolizing a pharmaceutical formulation, the method comprising:

providing a valve within an airway leading to the lungs to prevent respiratory gases from flowing to the lungs when a user attempts to inhale, and then abruptly permitting respiratory gases to flow to the lungs by opening the valve when a threshold actuating vacuum caused by the attempted inhalation is exceeded,

providing a flow regulator within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases, wherein the flow resistance through the flow regulator is low when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases thereafter; and

using the flow of respiratory gases to extract a pharmaceutical formulation from a receptacle and to place the pharmaceutical formulation within the flow of respiratory gases to form an aerosol.

54. A method as in claim 53 wherein the threshold actuating vacuum is in a range from about 20 cm H_20 to about 60 cm H_20.

55. A method as in claim 53 wherein the flow regulator limits the flow of respiratory gases to the lungs ~~is~~ to a rate that is less than a certain rate.

56. A method as in claim 55 wherein the certain rate is about 15 L/min.

57. A method as in claim 53 wherein the flow regulator regulates the size of the airway leading to the lungs.

58. A method as in claim 57 wherein the flow regulator comprises an elastomeric duckbill valve.

59. A method as in claim 53 wherein the valve and the flow regulator are provided in series.

60. A method as in claim 53 wherein the airway includes a parallel flow arrangement.

(9) Evidence Appendix

none

(10) Related Proceedings Appendix

none